

REMARKS

Introductory Comments

Applicants wish to express their appreciation for the telephonic discussion between the Examiner and the undersigned representative on October 14, 2010 wherein the outstanding rejections were discussed with regard to the pending claims. Applicants also express their appreciation that for the reasons of record, including the declaration under 37 CFR 1.132 filed May 8, 2009 showing synergistic rather than additive effects for the claimed combination, the rejection made under 35 USC 103(a) was withdrawn. Applicants acknowledge that the Examiner will consider re-joining and examining withdrawn claim 20 after further consideration of the arguments of record (re-presented in part below) to address the nonstatutory obviousness-type double patenting rejection of claim 1.

The Claims

In case linking claim 1 is found allowable, applicants expressly request rejoinder of withdrawn claim 20 for further examination.

The Rejections

Non-statutory Double Patenting

The Examiner has again rejected claim 1 under the judicially created doctrine of obviousness-type double patenting, as being unpatentable over claim 11 of U.S. Patent No. 6,498,178 (hereinafter the “‘178 patent”). Applicants respectfully traverse the rejection for the reasons of record which have been re-presented below.

As discussed in the § 103(a) rejection section of the Reply filed February 1, 2010, the combination of compound 181 and fludarabine in a therapeutically effective amount recited in claim 1 represents a non-obvious patentable invention over Montgomery and Stamos because it provides an unexpected synergistic effect resulting in an enhanced anti-cancer profile. By analogy, the presently claimed synergistic combination is an unobvious, patentable invention over the ‘178 patent because the ‘178 patent provides no teaching, suggestion or motivation to select the claimed combination in a therapeutically effective amount and expect it to have this synergistic anti-cancer effect.

Moreover, the Manual of Patent Examination Procedure (MPEP) states that “[a] double patenting rejection of the obviousness-type>, if not based on an anticipation rationale,< is ‘analogous to [failure to meet] the nonobviousness requirement of 35 U.S.C. 103’ ” (see MPEP § 804 II.B.1 quoting *In re Braithwaite*, 379 F.2d 594, 154 USPQ 29 (CCPA 1967)). The MPEP further states that “[t]herefore, *>the< analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. 103 obviousness determination” (see MPEP § 804 II.B.1 quoting *In re Braat*, 937 F.2d 589, 19 USPQ2d 1289 (Fed. Cir. 1991); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985)). The relevant factual inquiries are as set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) and include any objective indicia of non-obviousness. Importantly, if these indicia include evidence that the compounds possess superior and unexpected properties then such a showing should be sufficient to rebut a *prima facie* case of obviousness whether related to a § 103 rejection or a nonstatutory obviousness-type double patenting rejection.

Therefore, for all the reasons of record and those presented above, the present application is an unobvious, patentable invention over the ‘178 patent. Accordingly, applicants respectfully request that the examiner withdraw this nonstatutory obviousness-type double patenting rejection over the ‘178 patent.

Conclusion

Applicants respectfully request that the examiner consider the foregoing remarks and allow the pending claims to pass to issue.

Respectfully submitted,

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